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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,820

04/28/2005

Sonia Escaich

1721-82

2788

23117

7590

04/20/2006

NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/520,820	Applicant(s) ESCAICH, SONIA	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 11, 12 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-7-2005</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1645

### **DETAILED ACTION**

Applicant's election with traverse of Group III, as it reads on SEQ ID NO:28, in the reply filed on 1-30-2006 is acknowledged. The traversal is on the ground(s) that the examiner has not established a lack of unity under the PCT rules. This is not found persuasive because as outlined in the restriction requirement, the instant claims do not share a special technical feature that constitutes a contribution to the art. This finding is additionally supported by the fact that nucleic acids and polypeptides of the various claimed inventions were known in the art at the time the invention was made (see below).

The requirement is still deemed proper and is therefore made FINAL.

Applicant's request for the rejoinder of Groups VII-IX to the elected group is acknowledged. Applicant's arguments have been fully considered and deemed non-persuasive. Said groups constitute distinct inventions (see above) and will be examined as such. Applicant's request for the rejoinder of the method claims of Groups VII-IX if the product claims of Group III were found allowable is acknowledged. As outlined in the Restriction Requirement, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

The amendment filed on 1-30-2006 is acknowledged. Claim 20 has been amended. Claims 1-20 are pending. Claims 1-4, 11-12 and 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 5-10 and 13 are currently under examination

***Claim Objections***

Claim 8 is objected to because of the following informalities: Said claim contains an obvious typographical error. The phrase “areRNAs” should read “are RNAs”. Appropriate correction is required.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 differs from its parent claim (claim 5) only in the SEQ ID NOs recited. As the elected invention is limited to SEQ ID NO:28, claim 6 is in essence a duplicate of claim 5.

Claims 5 and 6 are objected to for reciting subject matter drawn to non-elected inventions.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-10 and 13 are rendered vague and indefinite by the use of the term “pathogenicity or virulence targets”. It is unclear what is meant by said term as it is not explicitly

Art Unit: 1645

defined in the specification. For what is said “pathogenicity or virulence target” a target? Does said term refer to bacterial products essential for proliferation? Moreover, how does a “pathogenicity target” differ from a “virulence target”? As written, it is impossible to determine the metes and bounds of the claimed invention.

The claim language used in claim 13 is confusing to the degree that it is impossible to determine what Applicant is claiming. What constitutes “products of expression” in the context of pathogenicity or virulence targets (which are polypeptides)?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7, 9-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Uniprot Database Accession No. P76658 (July 15, 1999 – IDS filed 1-7-2005).

The cited database entry discloses the sequence for *E. coli* rfaE said sequence being identical with SEQ ID NO:13 of the instant application. Said database entry further discloses that the disclosed amino acid sequence was derived from nucleic acid. Since SEQ ID NO:28 of the instant application encodes the protein with the amino acid sequence set forth in SEQ ID NO:13, the cited reference is deemed to anticipate all the limitations of the instant claims.

Art Unit: 1645

Claims 5-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zyskind et al. (WO 00/44906 – IDS filed 1-7-2005).

Zyskind et al. disclose a nucleic acid from *E. coli* with the sequence set forth in SEQ ID NO:28 of the instant application (see SEQ ID NO:165 on pages 55-56). Zyskind et al. further disclose that said nucleic acid can serve as a target for compounds with the ability to reduce the activity or level of a polypeptide required for proliferation (i.e. serves as a pathogenicity or virulence target) [see page 4, lines 32-35]. Finally, Zyskind et al. disclose that said nucleic acid could be messenger RNA (see page 5, lines 3-4) or cDNA (see Example 1). Consequently, Zyskind et al. anticipate all the limitations of the instant invention. It should be noted that Zyskind et al. also disclose the polypeptide encoded by SEQ ID NO:165 which is identical to SEQ ID NO:13 of the instant application (see SEQ ID NO:325 on pages 151-152).

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert Zeman', with a long horizontal flourish extending to the right.

ROBERT ZEMAN  
PATENT EXAMINER

April 6, 2006